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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Harrington *et al.*

Serial No.: Re. 09/586,744

Group No.: 1652

Filed: 06/02/00

Examiner: T. Saidha

Entitled: MAMMALIAN FLAP-SPECIFIC ENDONUCLEASE

PROTEST TRANSMITTAL LETTER

Assistant Commissioner for Patents

Washington, D.C. 20231

ATTN: John Doll and Tekchand Saidha

Group Art Unit: 1650

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

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By: Susan M. McClintock

REMARKS

This is a Protest for application no. Re. 09/586,744, filed 06/02/00. Third Party Protestors believe no fee is required but if the Commissioner deems otherwise he is authorized to charge Deposit Account No. 08-1290.

A copy of this Protest is also being forwarded on this day to counsel of record: Pennie & Edmonds, ATTN: Samuel B. Abrams, 1155 Avenue of the Americas, New York, NY 10036 in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10, Express Mail Label No. EK 898 390 653 US.

DATE: January 9, 2002

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Serial No.: Re. 09/586,744

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MAMMALIAN FLAP-SPECIFIC ENDONUCLEASE

**REISSUE APPLICATION PROTEST
UNDER 37 C.F.R. 1.291
TO ADDRESS NEW ISSUES**

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

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Dated: January 9, 2002

By:

Susan M. McClintock
Susan M. McClintock

Sir:

The following communication is presented to protest reissue application 09/586,744. Specifically, this communication is directed toward new issues that could not have been addressed in the previously filed Protest (mailed January 3, 2001).

REMARKS

In the previously filed Protest, four issues were addressed that are distinct from the new issues discussed in this communication. For the Examiner's convenience, the four issues are summarized below such that it is clear that the new issues presented herein are new issues that could not have been presented in the previously filed Protest.

1. In the previous Protest, it was pointed out that no proper "error" was identified or alleged as required for a reissue application, and therefore, the reissue, as a matter of law, could not proceed. Instead, Applicants elected composition claims (*without traverse*) in

the face of a restriction requirement, without ever pursuing the non-elected claims or other inventions in a divisional or continuation, thereby giving up such claims. Under controlling case law, this was a *choice*, not an error warranting reissue.

2. In the previous Protest, it was pointed out that the new claims are directed to separate and distinct subject matter that is not the "same invention" as required for a proper reissue application, and therefore, the reissue, as a matter of law, could not proceed. For example, the previous Protest highlighted the fact that the sixty-seven (67) new claims that had been added by amendment were all directed to alleged inventions that the inventors admit in sworn declarations they had not conceived of at the time the original application was filed.

3. In the previous Protest, it was pointed out that all of the claims sought to be added were drafted more broadly than the original six claims in an attempt by the new patent owner to improperly recapture what was surrendered during the prosecution of the application, and therefore, the Reissue, as a matter of law, could not proceed. Having surrendered the broader claims, as highlighted in the previous Protest, applicants could not then use the reissue process to resurrect this subject matter.

4. In the previous Protest, it was pointed out that all sixty-seven added claims were unsupported by the original specification, and to cover this deficiency, there was an improper attempt to bodily incorporate the contents of a non-patent document to provide support essential for the new claims, and therefore, the Reissue, as a matter of law, could not proceed. The previous Protest also highlighted the fact that even with such an improper amendment of the specification, all of the claims are still unsupported.

The present communication addresses two new issues based on misleading statements made by the Applicants. First, in response to the Examiner's New Matter rejection, Applicants now allege to have made a *specific* incorporation of double-flap structures. However, the case law cited by the Applicants fails to support Applicants' position, and Applicants failed to disclose that the '283 specification *specifically contradicts* incorporation of double-flap structures.

Second, in response to the Examiner's Written Description rejection, Applicants attempt to re-define double-flap structures in a manner *inconsistent* with the '283 specification's clear definition of 3' flap structures. This attempt to re-define double flap structures as outside the definition of 3' flap structures is important since the '283 specification specifically recites that 3' flap structures are not cleaved by FEN-1. Protestors note that the misleading statements made by Applicants represent new issues from the four issues previously addressed, and could not have been presented in the first Protest as the misleading statements had not yet occurred. As such, this protest is proper under 37 CFR 1.291, and should be made part of the public record of this reissue application.

I. Applicants Did Not Specifically Incorporate Double-Flap Structures

In response to the Examiner's New Matter rejection, Applicants have attempted to convince the Examiner that the '283 Specification "specifically" incorporated double-flap structures into the body of the application (See, November 26, 2000, "Communication", pg 1, and Amendment Under 37 CFR § 1.111, hereinafter "Amendment", pgs 6-12). For example, Applicants allege that the '283 specification "makes *specific reference to specific subject matter* - flap substrates, cleavage reactions and binding reactions - and identifies where it may be found" (Amendment Under 37 CFR § 1.111, hereinafter "Amendment", pg 7). Applicants cite *In re Voss*¹ to support their position, stating "[s]uch specific references have long been considered effective to incorporate the referenced subject matter into the disclosure of the referencing application." (Amendment, pg 9). However, an examination of *In re Voss*, and the contradictory statements in the '283 specification regarding 3' flap structures make it clear that Applicants have not legally incorporated double-flap structures into the specification.

A. *In re Voss*

Applicants liken the present situation with that of *In re Voss*. However, this comparison is not valid once the court's reasoning in *In re Voss* is examined. In particular, the purpose of the incorporation in *In re Voss* was "to incorporate a discussion of glass-ceramic articles and methods of preparing them" (Id. at 817). In allowing the incorporation by reference, the court

¹ *In re Voss*, 557 F.2d 812; 194 USPQ 267 (CCPA, 1977).

specifically acknowledged that "[g]lass-ceramic material are *merely starting materials* for appellant's strengthening process," and "[r]ather than include in his application a detailed discussion of how to prepare such *known* starting materials, appellant, for economy, referred the skilled artisan to Stookey '971" (*Id.*, *emphasis added*). In the present case, it is clear that Applicants are trying to incorporate more than mere starting materials as the double-flap structures are central to all of the new claims (*See, e.g.*, Claim 51), but are completely absent from the Specification (i.e. there is no reference or suggestion that double-flap structures were contemplated in any composition or method). Furthermore, Applicants could not reasonably argue that the double-flap structures they are attempting to incorporate were "known" since they have specifically argued that the claimed double-flap structure is novel (*See*, Amendment, pg 23). Therefore, while the *In re Voss* decision is instructive,² it does not support Applicants' position that double-flap structures have been legally incorporated by reference.

B. Applicants' "Specific" Reference is *Contradicted* by the '283 Specification

As mentioned above, in response to the Examiner's New Matter rejection, Applicants, in two recent communications, have attempted to convince the Examiner that the '283 Specification "specifically" incorporated double-flap structures into the body of the application. However, Applicants failed to disclose that the '283 specification *specifically contradicts* incorporation of double-flap structures. The fact that double-flap structures are specifically not contemplated in the '283 patent is evident when the entire '283 specification is considered.

For example, the '283 patent, consistently defines "3' flap structure" in such a manner the indicates that Applicants never intended double-flap structures to become part of the of the original patent disclosure. Specifically, the '283 patent gives "3' flap structure" a specific meaning in the specification:

1. "Conversely, 3' flap structures have a flap strand that terminates with a 3' single-stranded end." (from col. 19, lines 16-18, in section entitled "Overview");

² For example, *In re Voss* identifies a proper incorporation by reference statement as "clearly identifying the subject matter which is incorporated and where it may be found." (*Id.*, citing *In re de Seversky*, 177 USPQ 144, which is the same case cited by the Examiner).

2. "Likewise, 3' flap structures have a flap strand which terminates in a 3' end." (from col. 44, lines 9-10, in section entitled "Experimental Examples"); and
3. "Conversely, 3' flap structures have a flap strand that terminates with a 3' single-stranded end." (from col. 50, lines 59-61, in section entitled "Experimental Examples").

This definition of 3' flap structures is consistent throughout the specification, and is NEVER given in the alternative (i.e. according to the definition above, if a structure has a flap strand with a 3' end, then it is considered a 3' flap structure according to the '283 specification).

Looking at the double-flap structure Applicants are attempting to incorporate by reference, according to the definition in the '283 patent, the double-flap structure IS a 3' flap structure since it has a flap strand with a 3' end. This is important because the '283 patent consistently teaches that FEN-1 does not cleave 3' flap structures. Specifically, the '283 patent states:

1. "FEN-1 specifically cleaves 5' flap structures and nicked DNA but does not 3' flap structures" (from col. 19, lines 28-29, in section entitled "Overview").
2. "FEN-1, which specifically cleaves 5' flap structures but not 3' flap structures." (from col. 50, lines 64-65, in section entitled "Experimental Examples").

In other words, the '283 patent consistently teaches that 3' flap structures³ could not be successfully practiced with the FEN-1⁴ methods and compositions in the '283 patent. Therefore, in light of this *specific* teaching in the '283 patent, it is clear that Applicants alleged "specific" incorporation by reference fails since it would be *inconsistent* with the specific teachings of the '283 patent.

The failure of the incorporation by reference statement becomes even more apparent

³ It is noted that the '283 patent consistently indicates that 3' flap **structures** cannot be cleaved by FEN-1. This is important to keep in mind since Applicants may attempt to mislead the Examiner with a non-relevant discussion of 3' flap **strands**.

⁴ It is also anticipated that Applicants will now argue that the cleaving properties of FEN-1 are not relevant to the present claims. However, the Examiner is reminded that applicants have previously argued:

"Specifically, the definition of FEN-1 makes it clear that this expression is generic in scope. The entire disclosure teaches that FEN-1 is an endonuclease capable of specifically cleaving certain polynucleotides." (Amendment Under 37 CFR 1.111, pg 22).

when the portion of the '283 patent trumpeted by the Applicants as providing "*specific* reference to *specific* subject matter" is examined. The passage quoted by Applicants on page 8 of the Amendment is reproduced below:

"DNA flap substrates, cleavage and binding reactions and the like *are practiced with reference* to the Experimental Examples and . . . Harrington & Lieber (1995) *J. Biol. Chem.* 270:4503."

This text from the '283 patent, far from making specific reference to double-flap structures, confirms the point that the '283 patent does not incorporate such structures. This is evident as this passage specifically references the **Experimental Examples** for practicing DNA flap substrates, cleavage and binding reactions. As notes above, the Experimental Examples define 3' flap structures to include double-flap structures, and then goes on to specifically teach that such structures cannot be successfully practiced with the FEN-1 methods and compositions in the '283 patent. As such, even the very passage cited by Applicants demonstrates that Applicants' attempted incorporation by reference is inconsistent with the plain teachings of the '283 patent. Therefore, while it is unclear what Applicants were trying to incorporate by reference, it IS CLEAR that it was not 3' flap structures, including double-flap structures.

C. Lack of Proper Written Description - *In re Kaslow*

Protestant also wish to point out that EVEN IF the Examiner allowed the double flap structures to be added to the '283 patent, the newly present claims still fail the written description requirement. The fact that the newly presented claims would still lack written description support is clear in light the *In re Kaslow*⁵ decision cited by the Applicants. The written description test is articulated in *In re Kaslow*:

"The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification." (Id. at 1375, *emphasis added*).

While Applicants cited this same test,⁶ they failed to provide the text underlined above indicating

⁵ *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983).

⁶ Applicants may point out that they also cited the *Ralston Purina Co.* decision. However, the written description test in *Ralston Purina* cites *In re Kaslow* as the source of the test.

what the test is NOT (i.e. they failed to indicate that the written description test is not based on the presence or absence of literal support in the specification). Therefore, it is respectfully submitted that even if the double flap structures are added to the specification, the claims fail the written description test since the '283 specifically teaches that 3' flap structures could not be successfully practiced with the FEN-1 methods and compositions in the '283 patent. As such, it is clear that the '283 patent would not convey to the skilled artisan that the inventors had possession of the invention as required to find proper written description support.

II. Applicants Attempt to Re-Define Double-Flap Structures

The Applicants have attempted to re-define double-flap structures in a manner *inconsistent* with the '283 patent's clear definition of 3' flap structures. The Applicants' attempt to define double-flap structures in a manner contradictory to the plain language of the '283 patent is demonstrated in the following statement from page 12 of the Amendment:

"A specific embodiment of the methods is illustrated with reference to a particular species of such a 5'-flap structure, the 5'-single flap structure depicted in FIG. 6 (see, e.g., Col. 43, lines 25-29). Additional 5'-single flap structures and another species of such 5'-flap structure, a 5',3'-double flap structure, are taught in the material incorporated by reference discussed previously (*see, e.g., Harrington & Lieber at page 4506*)" (*emphasis added*).

As seen in this above statement, Applicants have gone to great lengths in order to convince the Examiner that double-flap structures are merely "another species" of 5'-flap structures. Applicants, of course, are trying to avoid the definition of 3' flap structures provided in the '283 patent since the '283 patent teaches that 3' flap structures cannot be successfully practiced with the methods and compositions in the '283 patent (*i.e.* since the '283 teaches that 3' flap structures are not cleaved by FEN-1).

Protestant submit that the above quoted statement is misleading as it characterizes double-flap structures as just another species of 5' flap structures. There are a number reasons why this is misleading. First, Applicants specifically argue that double-flap structures are simply a species of 5' flap structures despite the fact that they knew (or should have known) that double-flap structures qualify as 3' flap structures according to the '283 patent. Second, while it appears that Applicants are pointing to support for the allegation that double-flap structures are simply a species of 5' flap structures, no such statements are found in the '283 patent. For example,

Applicant use the phrase "5'-single flap structure" as if it commonly appears in the '283 patent. However, this phrase NEVER appears in the '283 patent as suggested by the Applicants. Likewise, Applicants use the phrase 5',3'-double flap structure as if it appears in the '283 patent. However, this phrase also NEVER appears in the '283 patent as suggested by the Applicants. Protestants also note that the phrase 5',3'-double flap structure never even appears in the Harrington & Lieber reference despite the fact that Applicants cite this reference in support of their statement.

As such, it appears that Applicants have recently come up with the phrase 5',3'-double flap structure, hoping that by placing the 5' at the beginning of the phrase, the Examiner would be convinced that double-flap structures are simply a species of 5' flap structures, and thereby ignore the fact the '283 patent's definition of 3' flap structures includes double-flap structures. It is also noted that Applicants have previously attempted to introduce a similar phrase into the 283' Specification that contradicts Applicants' position that double-flap structures are simply a species of 5' flap structures. In particular, the Preliminary Amendment filed on June 2, 2000 by Applicants does not attempt to introduce the phrase 5',3'-double flap structure into the specification, but DOES attempt to introduce the phrase 3',5'-double flap structures into the specification (*See*, page 5 of the Preliminary Amendment, line that reads "various (sic) 5'-flap structures and 3',5'-double flap structures."). Applicants' use of the phrase 3',5'-double flap structures appears to contradict Applicants' new assertion that double flap structures are merely a species of 5'-flap structures.

CONCLUSION

As highlighted above, the '283 patent does not support the incorporation of double-flap structures as alleged by the Applicants. Furthermore, even if double-flap structures are added to the specification, the newly added claims still fail the written description test. For these reasons, in addition to the issues discussed in the previous Protest, Protestants believe the newly added claims in the reissue application should be rejected by the Examiner.

Applicants are attempting to rewrite the patent laws in their attempt to now patent subject matter that was not part of their original specification or invention. Protestants encourage the Examiner not to allow this rewriting or reinterpretation of the patent laws. Such a task is left to Congress or the Courts.

Dated: January 9, 2002



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